

Attorney Docket No.: 930008-2208 (BOE0004US.NP)
Inventors: Klokke et al.
Serial No.: 10/577,569
Filing Date: February 27, 2008
Page 7

REMARKS

Claims 1-31 are pending in this application. Claims 1-31 have been canceled. Claims 32-61 have been added. No new matter has been added. Applicants respectfully request reconsideration of the restriction requirement in view of the following remarks.

Claims 1-31 have been subjected to a Restriction Requirement under 35 U.S.C. §121 and §372 as follows:

Group I, claims 1 to 27, drawn to a pharmaceutical active-ingredient-containing formulation;

Group II, claims 28-30, drawn to an aqueous dispersion for the preparation of a coating; and

Group III, claim 31, drawn to a process for the preparation of a pharmaceutical active-ingredient-containing formulation.

The Examiner suggests that the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

The Examiner suggests that the special technical feature of Group I is the oral pharmaceutical formulation comprising an active ingredient coated with a film-forming polymer which is comprised of two separating agents and no stabilizer. The Examiner contends that the oral pharmaceutical formulation comprising an active ingredient coated with a film-forming polymer which is comprised of two separating agents and no stabilizer of claim 1 does not present a contribution over the prior art because US patent application publication 2003/0133983 discloses an oral pharmaceutical formulation comprising an active ingredient coated with a film-forming polymer which is comprised of two separating agents and no stabilizer. The Examiner

Attorney Docket No.: 930008-2208 (BOE0004US.NP)
Inventors: Klokke et al.
Serial No.: 10/577,569
Filing Date: February 27, 2008
Page 8

concludes that Group I does not share a special technical feature with the instant claims of Group(s) II-III and therefore unity between Groups I-III is lacking. Applicants are required to elect one group to be examined.

In addition, the Examiner has required Applicants to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, Applicants are to elect one specific separating agent that floats in pure water, one specific separating agent that sinks in pure water and one specific film forming polymer.

The Examiner has required restriction between product and process claims and acknowledges that where Applicants elect claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. Applicants respectfully disagree and traverse this restriction requirement and election of species.

Applicants respectfully disagree with this restriction requirement. The present invention features an aqueous dispersion for the preparation of a coating for a pharmaceutical active-ingredient-containing formulation for oral administration. Accordingly, in an earnest effort to facilitate the search and examination of the subject matter of this application, Applicants have canceled claims 1-31 and presented new claims 32-61, which focus on the method for preparing the aqueous dispersion of claims 28-30. Support for new claim 32 is found in the last paragraph at page 23 of the specification as filed and in claims 28-30 as originally filed. Support for new claims 33-42 is

Attorney Docket No.: 930008-2208 (BOE0004US.NP)
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Serial No.: 10/577,569
Filing Date: February 27, 2008
Page 9

respectively found in claims 4-6, 9-13, and 15-16 as originally filed. Support for new claim 43 is found at page 23, last paragraph, of the specification as filed. Support for new claim 44 is found at page 24, lines 1-2, of the specification. Support for new claims 45-47 is respectively found in claims 17-19 as originally filed. Support for new claims 52-55 is found in claim 21 as originally filed. Support for new claims 56-57 is found in claim 24 as originally filed. Support for new claims 58-59 is found in claim 25 as originally filed. Support for new claims 60-61 is found in claim 27 as originally filed. In light of this amendment to the claims, Applicants respectfully believe that unity of invention exists for the claims as currently presented and therefore withdrawal of the restriction requirement is respectfully requested.

In so far as the claims as currently presented read on fatty acid salt as a separating agent that floats in pure water and layer silicate as a separating agent that sinks in pure water, it is also respectfully requested that the requirement for an election of particular species of separating agent that sinks or floats in pure water be reconsidered and withdrawn. Moreover, because the film-forming polymers of the claimed process each have the characteristic of forming a film, said polymers function in the same manner in the instant dispersion. As such, a search of each species within the genera is co-extensive and no serious burden would be incurred by the Examiner in searching and examining the genera. In contrast, the prosecution of each of the disclosed species separately will pose a substantial economic burden on Applicants. Therefore, reconsideration of this species election is respectfully requested.

Attorney Docket No.: 930008-2208 (BOE0004US.NP)
Inventors: Klokke et al.
Serial No.: 10/577,569
Filing Date: February 27, 2008
Page 10

In light of the cancellation of claims 1-31 and presentation of new claims 32-61, Applicants hereby elect to prosecute claims 32-61, drawn to a process for the preparation of an aqueous dispersion. Moreover, in an earnest effort to be completely responsive, Applicants also make the provisional election of polyacrylate as film-forming polymer.

Respectfully submitted,

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